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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/380,738 | 12/06/99 | REYNOLDS | E 040268/0161 |

HM22/0517

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
| 1653 | 7 |

DATE MAILED: 05/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/380,738

Applicant(s)

Reynolds

Examiner

David Lukton

Group Art Unit
1653



☒ Responsive to communication(s) filed on Dec 6, 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire **30 DAYS** or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-36 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to preliminary amendment, claims 4-6, 10-20, 22, 25, 27 have been amended. Applicants have also directed the addition of claims 29 and 30; however, there were 36 claims present in the application as filed. This latter portion of the amendment has not been entered. It is suggested that applicants direct the addition of claims numbered 37 and 38.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1-6, 15-24, 29-34, drawn to a complex which requires the presence of fluoride, classified in, e.g., 514/007.
- II. Claims 7-16, 29, drawn to a complex which does not require the presence of fluoride, classified in, e.g., 514/007.
- III. Claims 25-28, 35, drawn to a method of using the complex of Group I, classified in, e.g., 514/007.

Claim 36 is not grouped, since it is a method which is dependent on claim 8; claim 8, in turn, is not drawn to a method, but is instead drawn to a complex *per se*. Claims 29 and 30, which applicants have directed the addition of, have also not been grouped, since the claim numbers are too low; however, if claim 29 is renumbered 37, and claim 30 is renumbered 38, then claim 37 will be assigned to group I, and claim 38 will be assigned to

both Group I and Group II, depending on the requirement for fluoride.

The claimed inventions are distinct.

Each of claims 15 and 16 is regarded as encompassing two separate inventions, one which requires the presence of fluoride, and one which does not; accordingly, claims 15 and 16 appear in both Group I and Group II. Similarly, claim 29 encompasses complexes which require fluoride, and those which do not.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because. The subcombination has separate utility such as use in treating bone disorders.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). The claimed complexes could be used to prevent tooth decay, or to treat osteoporosis. However, in the event that claims drawn to a complex are elected and subsequently found allowable, the corresponding method-of-use claims will be rejoined for

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Art Unit 1653

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further examination [*In re Ochiai* (37 USPQ2d 1127)].

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A specie is a specific peptide, with all amino acids accounted for; if a given peptide "X" is described as "containing" or "including" another peptide, then peptide "X" is not a specie, but is instead a sort of genus.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


DAVID LUKTON
PATENT EXAMINER
GROUP 1800